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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/694,641	10/27/2003	Deanna L. Kroetz	023070-115611US	4011

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EXAMINER

KWON, BRIAN YONG S

ART UNIT	PAPER NUMBER
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1614

MAIL DATE	DELIVERY MODE
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05/11/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/694,641	Applicant(s) KROETZ ET AL.	
	Examiner Brian S. Kwon	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 46-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 46-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application

1. Acknowledgment is made of applicant's filing of an amendment on 02/23/07. By the amendment, claims 14-45 have been cancelled and claims 46-49 have been added. Claims 46-49 are currently pending for prosecution on the merits of the case.
2. Acknowledgement is made of applicant's filing of Terminal Disclaimer. Accordingly, the submitted Terminal Disclaimer has been approved and placed in the file record.
3. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of actions being applied to the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 46-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 46-49 are unclear of what "which inhibitor or a pharmaceutically acceptable salt thereof" refers to. Does it refer to the preceding "an inhibitor of soluble epoxide hydrolase"? There is insufficient antecedent basis for this limitation in the claim.

This rejection could overcome by amending "which inhibitor" to " , wherein said inhibitor".

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With respect to claims 47 and 49, the claims contain acronyms, for example nb 20, nb 21, nb 22, nb 23, nb 36, etc... Where acronym is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. The claim scope is uncertain since the acronym cannot be used properly to identify any particular material or product. An acronym is used to identify a source of goods, and not the goods themselves. In this regard, although the compounds are shown in the Table I, it is considered that the meaning of the claims should be clear from the wording of the claim alone.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 46 and 48 are rejected under 35 U.S.C. 102(b) as being anticipated by Ichihara et al. (JP 07304755).

Ichihara teaches use of compounds (e.g., RN 174398-90-4, RN 174398-91-5, RN 174398-92-6, RN 174398-93-7, etc...) or their salt, which reads on the instantly claimed compounds of the formula 1, for the treatment of the claimed cardiovascular disease such as hypertension by modulating rennin-angiotensin system, wherein said compound is administered in various dosage forms including oral dosage forms (i.e., tablet, capsule), see para. [0001], [0035] and Table I). Ichihara discloses that a rennin inhibitor tends to control generation of angiotensin II which works powerfully to pressure ups, such as a vasoconstrictor action and

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aldosterone secretion, by checking the reaction of the rennin and rennin substrate (angiotensionogen) which are called rate-determining step of the renin-angiotensin series which is a pressure-up system in the living body, and reducing generation of angiotensin I (para. [0002]).

6. Claims 46 and 48 are rejected under 35 U.S.C. 102(e) as being anticipated by Blum et al. (US 5962455).

Blum teaches use of compounds (e.g., RN 202472-67-1, RN 202472-68-2, RN 202472-69-3, RN 202472-70-6, etc...) or their salt, which reads on the instantly claimed compounds of the formula 1, for the treatment of the claimed cardiovascular disease such as hypertension or essential hypertension as well as congestive heart failure, wherein said compound is administered in dosage amounts of from about 0.1mg to about 140mg per kilograms of body weight per day and in various dosage forms including oral dosage form (abstract; column 1, line 39; column 1, line 45 thru column 3, line 15; column 7, line 51; column 8, line 52 thru column 10, line 62).

Response to Arguments

7. Applicant's arguments/Declaration filed 02/23/07 have been fully considered but they are not persuasive.

Applicant's argument in the response takes the position that any urea based compound of the prior art that is taught as having anti-hypertensive activity is de factor acting as an sHE inhibitor is both factually and legally in error. Applicant alleges that compounds which might otherwise fall within the genus of structures encompassed by the claims are not encompassed by

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the claimed methods unless they (1) are sHE inhibitors and (2) can be administered in therapeutically effective amounts.

This argument is not found persuasive. As the applicant also acknowledged, the prior art compounds disclosed in either Ichihara or Blum overlap with the genus of compounds represented by the claimed structure. Furthermore, the prior art compounds are taught to be useful as same purpose as the instant invention, for the therapeutic utility in reducing blood pressure and/or treating hypertension. Thus, regardless of the alleged sHE inhibiting activity of the compounds, the claimed method is clearly taught in the prior art. The fact that the applicant may have discovered a new pharmacological mechanism (sHE inhibiting activity) for a compound represented by the claimed structure is not considered patentably distinctive over the prior art which are directed to the same ultimate purpose (for the treatment of hypertension).

Anticipation under 35 USC 102 is an essentially irrebuttable question of fact, wherein the court stated that anticipation “cannot be overcome by evidence of unexpected results or teachings away in the art”. *In re Malagari*, 499 F.2d 1289, 182 USPQ; *In re Spada*, 911 F.2d 705, 15 USPQ2d 1655 (Fed. Cir. 1990); *In re Fracalossi*, 681 F.2d 792, 215 USPQ 569 (CCPA 1982); *In re Altermohl*, 500 F.2d 1151, 183 USPQ 38 (CCPA 1974); *In re Wiggins*, 488 F.2d 538, 179 USPQ 421 (CCPA 1973); *In re Wilder*, 429 F.2d 447, 166 USPQ 545 (CCPA 1970). Indeed, a reference might reside in a nonanalogous art and yet constitute an anticipation of a claimed invention under 35 USC 102. *In re Self*, 571 F.2d 134, 213 USPQ 1 (CCPA 1982).

Conclusion

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8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (571) 272-0581. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached on (571) 272-0718. The fax number for this Group is (571) 273-8300.

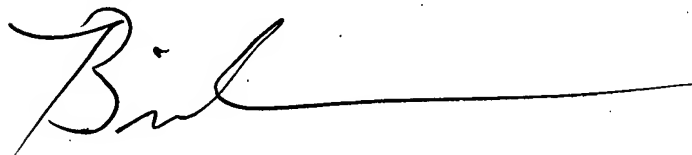
Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

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may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications may be obtained from Private PAIR only. For more information about PAIR system, see <http://pair-direct.uspto.gov> Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Brian Kwon
Primary Patent Examiner
AU 1614

A handwritten signature in black ink, appearing to read 'Brian', followed by a long horizontal line extending to the right.